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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,688	08/07/2000	JIMMIE L. JOHNSON	J-135CIP	3622

7590 05/19/2004

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EXAMINER
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MACHUGA, JOSEPH S

ART UNIT	PAPER NUMBER
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3762

12

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/633,688

Applicant(s)

JOHNSON, JIMMIE L.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

Applicant's arguments have been given careful consideration but are not deemed persuasive. Smith #2653611 discloses the basic environment of a medical container having a first frangible lid and a second outer lid. The references to either Smith #2275567 or Crankshaw et al #4089432 both provide teachings to add an additional outer cover for the purpose of providing a sanitary environment. Therefore, the rejection under 35 USC 103 is considered proper. Likewise, Barasch et al #2764983 teaches adding a well to a container to enable the needle to withdraw more liquid. Therefore the rejection of newly presented claim 32 is also considered proper.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 30–39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 line 9 and claim 34 line 10 lack antecedent basis for the second and third lid.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 30, 31, 34, 35, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith #2653611 in view of Smith #2275567.

3. Smith #2653611 discloses a sterile medical container having a first frangible lid (17,23), and a second outer lid (28) having a syringe receiving stopper (31). Not disclosed by this reference in the third sterile lid. Smith 2275567 discloses a sterile medical container having a frangible member. The reference teaches adding a third outer lid (100) to a medical container help maintain a sterile environment. The reference also teaches using a capsule to deliver the solid component. Given this teaching by Smith #2275567 it would have been obvious to one of ordinary skill in the art to add an outer lid to Smith's #2653611 medical container to keep contaminants off it's outer surface. To use a capsule to deliver the solid component of the mixture would also have been obvious given Smith's teaching that this provides a simplified method of delivery. The method steps would be provided for by the proposed combination since Smith #2653611 functions in the manner claimed.

4. Claims 30, 33, 34 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith #2653611 in view of Crankshaw et al #4089432.

Smith #2653611 discloses a sterile medical container having a first frangible lid (17,23), and a second outer lid (28) having a syringe receiving stopper (31). Not disclosed by this reference in the third sterile lid. Crankshaw et al #4089432 discloses a medical container. The reference teaches add an outer sterile lid to a container to keep contaminants off the stopper. Given this teaching by Crankshaw et al #4089432 it would have been obvious to one of ordinary skill in the art to add an outer lid to Smith's #2653611 medical container to keep contaminants off the stopper. The method steps would be provided for by the proposed combination since Smith #2653611 functions in the manner claimed.

5. Claim 32 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith #2653611 in view of Smith #2275567 or Smith #2653611 in view of Crankshaw #40894332 as applied to claim 30 above, and further in view of Barasch et al 2764983.

6. Barasch et al discloses a mixing vial. The reference teaches adding a well to the container to assist in withdrawing all the material from the vial.

7. Given Barasch et al disclosure it would have been obvious to one of ordinary skill in the art to add a well to the container of the proposed combination of either Smith

#2653611 in view of Smith #2275567 or Smith #2653611 in view of Crankshaw to enable a syringe to withdrawal the last drop of liquid.

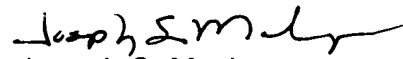
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700